

Tina Kotek, Governor

**McCowan Clinical Laboratory, Inc.**

**ORELAP ID: OR100026**

### Settlement Agreement

This Stipulated Settlement Agreement (“Agreement”) is made and entered into by and between **Oregon Health Authority, Oregon Environmental Laboratory Accreditation Program**, (“ORELAP”) and **McCowan Clinical Laboratory, Inc.** (“Accreditee”) (collectively, “the parties”). Parties wish to resolve the violations discovered during ORELAP’s investigation of Accreditee’s facility as described below. It is therefore agreed and stipulated by and between the parties as follows:

#### **Background**

1. Accreditee operates a laboratory located at 178 W Commercial Street, Coos Bay, OR 97420 (premises).
2. ORELAP renewed Accreditee’s certificate ORELAP ID #OR100026 (“accreditation”) on 10/07/2024. Accreditation is required to perform testing of drinking water for compliance reporting to Oregon Health Authority’s Drinking Water Services.
3. ORELAP conducted a routine biennial inspection at Accreditee’s premises on March 19<sup>th</sup> and 20<sup>th</sup>, 2025 (“inspection”). During the inspection, ORELAP discovered violations regarding Accreditee’s incubation equipment and methods as described in this Agreement.
4. Accreditee’s continued operation due to the incubation violations posed a serious and immediate risk to public health and safety as described in this Agreement and immediate suspension of Accreditee’s accreditation to perform testing for *Escherichia coli* (*E. coli*) and Total coliforms for drinking water effective immediately was necessary.
5. As an alternative to an emergency suspension order, ORELAP offered Accreditee the option to voluntarily withdraw its accreditation for testing for *E. coli* and Total coliforms for drinking water. Accreditee voluntarily agreed to

request withdrawal of its accreditation for drinking water and submitted the request on March 27, 2025 (“withdrawal”) which ORELAP approved the same day. Accredittee was aware of its rights to a contested case hearing if it elected not to voluntarily withdraw its accreditation and ORELAP proceeded with formal action to immediately suspend. Accredittee was aware of its rights to judicial review. Accredittee freely and voluntarily waived all rights to a contested case hearing and to all judicial review by voluntarily submitting its withdrawal.

### **Incubation Requirements**

6. To produce accurate results, laboratory equipment must maintain stable incubation temperatures inside the allowable range for the duration of the required sample incubation period. Testing of samples incubated outside of the allowable temperature range could result in false negative results because the temperature is too low or too high to allow for the growth and metabolic function of any bacteria present in the sample. Without the growth and metabolic activity of the bacteria, the test will not accurately detect bacteria. Presence of these pathogenic bacteria in drinking water samples could indicate the presence of pathogenic bacteria in the publicly consumed drinking water where the samples were obtained.
7. Pathogenic bacteria in publicly consumed drinking water could cause serious illness or death and is in violation of the national primary drinking water regulations. Accurate detection of pathogenic bacteria in public drinking water is essential to public health and safety and failure to do so may result in serious illness or death to water users. Detection triggers notice to be provided to water users so they can avoid the water if necessary. Detection allows water providers to take necessary measures to prevent harm to public health and safety including corrective actions to remove and prevent future contamination. (40 CFR Part 141.851-141.861.)

### **Accredittee’s Technical Requirements**

8. Under its accreditation for testing drinking water, Accredittee was subject to the following requirements:
  - a. Standard Methods (SM) 9223 B 20<sup>th</sup> Edition (hereinafter SM 9223 B) in both a presence/absence (Colilert®) and quantitative (Colilert®-18

Quanti-Tray®) format, an analytical method allowed under federal rule to test for Total Coliforms and *E. coli*.

- b. Per SM 9223 B, incubate samples at 35 +/- 0.5°C and also as specified in the manufacturer's instructions. SM 9223 B, Section 2.
- c. Per SM 9223 B, comply with manufacturer's instructions for the Colilert® test system which specifies incubation at 35 +/- 0.5°C.
- d. Per the TNI Standards, verify and record incubator temperature twice daily at least four hours apart. 2016 TNI Standard, V1M5 1.7.3.7.b.v.b.

### **Accreditee's Incubation Laboratory Equipment**

9. Accreditee's laboratory equipment used to incubate drinking water samples for the Total Coliforms and *E. coli* were outside of the allowable temperature range of 35 +/- 0.5°C on at least 16 instances between March 2024 and February 2025, as specified in Attachment A, incorporated by reference herein.

### **Violations**

10. Accreditee committed the following violations:
  - a. Accreditee failed to implement a quality system as required by TNI Standards on sixteen instances between March 2024 and February 2025 in violation of OAR 333-064-0035(2)(b)(D). TNI Standards require Accreditee to carry out testing to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition. TNI Standards, Volume 1, Module 2, 4.1.2 (incorporated by OAR 333-064-0015 and 333-064-0035(2)(b)(D)). As water suppliers, Respondent's customers needed testing that complies with OAR 603-061-0036 and 40 CFR Part 141. To comply with these state and federal rules, based on Accreditee's chosen testing methodology, Accreditee was required to incubate samples in a temperature range of 35 +/- 0.5°C. Accreditee failed to comply with this requirement on at least sixteen occasions between March 2024 and March 2025. In addition, as a general matter, Accreditee's clients contracted with Accreditee to test for Total Coliforms and *E. Coli*, but Accreditee's testing would not reliably detect those organisms due to the improper incubation. Accreditee's testing did not satisfy the needs of the customer in violation of the TNI Standards and OAR 333-064-0035(2)(b)(D). Each occasion is a separate violation of

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these requirements and could be subject to civil penalties not to exceed \$500 per day per violation.

b. Accreditee also failed to have a quality system because TNI Standards require that the laboratory have personnel to identify departures from procedures for performing tests. TNI Standards, Volume 1, Module 2, 4.1.5(a) (incorporated by OAR 333-064-0015 and 333-064-0035(2)(b)(D)). Accreditee's staff recorded the departures of the incubator from the required temperature range but failed to identify this as a departure from procedures or to initiate actions to prevent or minimize the departure on at least sixteen occasions between March 2024 and March 2025. Each is a violation of OAR 333-064-0035(2)(b)(D). Each occasion is a separate violation of these requirements and subject to civil penalties not to exceed \$500 per day per violation.

11. Because of the above violations, Accreditee's continued accreditation to test drinking water constituted a serious danger to public health or safety. ORS 183.430(2); OAR 137-003-0560(1). ORELAP had grounds to immediately suspend Accreditee's accreditation for testing of drinking water for Total Coliforms and *E. coli* bacteria. ORS 183.430(2); OAR 137-003-0560(1).
12. Accreditee's violations are subject to civil penalty in the amount of up to \$16,000 for 32 violations at a penalty of \$500 per violation.

### **General Terms**

13. Accreditee admits to the violations described above, and the facts underlying those violations.
14. ORELAP agrees not to impose a civil penalty or other disciplinary action for the violations above as they pertain to Accreditee's accreditation to test drinking water. Consistent with applicable state laws and rules, ORELAP may rely on the violations to evaluate future applications or determining the extent or appropriateness of any future action or sanction. Accreditee waives the right to contest the violations and facts described in the Agreement now and in any future action by ORELAP regarding those violations.

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- 15.** Accreditee agrees to implement the corrective action report below for continued accreditation for testing non-potable water for Total Coliforms and *E. coli* bacteria.
- 16.** If Accreditee does not perform any of its responsibilities in this Agreement, ORELAP may proceed with disciplinary, penalty, or other enforcement action against Accreditees accreditation or any future accreditation. If Accreditee fails to comply with this Agreement, ORELAP shall notify Accreditee of the violation and provide the opportunity for a contested case hearing, but the only issue Accreditee may contest is whether it failed to comply with the Agreement.
- 17.** If ORELAP discovers any additional violations or conduct beyond what is described in this Agreement, ORELAP may proceed with disciplinary, penalty, or other enforcement action. Accreditee would have notice and opportunity to contest any such action in a contested case proceeding.
- 18.** Accreditee may apply for accreditation to test drinking water for Total Coliforms and *E. coli* in accordance with OAR Chapter 333, Division 64 at any time if in compliance with this agreement. ORELAP shall process the application in accordance with applicable statute and rules and may consider the violations in this Agreement when reviewing the application as permitted by state law and may deny the application if not in compliance with this agreement. If Accreditee fails to comply with this Agreement, ORELAP shall notify Accreditee of the violation and provide the opportunity for a contested case hearing, but the only issue Accreditee may contest is whether it failed to comply with the Agreement.
- 19.** Nothing in this Agreement precludes other state or federal agencies, including but not limited to other units of OHA, from asserting criminal, civil, or administrative claims against Accreditee based on the facts underlying the Agreement. Nothing in this Agreement prevents Accreditee from disputing such matters and presenting evidence to dispute such matters and asserting affirmative defenses.
- 20.** Accreditee releases and waives any and all claims of any kind, known or unknown, past or future, against the State of Oregon or its agencies, instrumentalities, employees, officers, or agents arising out of the matters set

forth in the Agreement, including but not limited to any claim under federal or state law for damages, declaratory or equitable relief, under 42 USC § 1983 et seq, and for attorney's fees or costs.

21. Accreditee is a Domestic Business Corporation. Gayle Troyer is a Registered Agent and President of McCowan Clinical Laboratory, Inc. Accreditee represents and warrants that Gayle Troyer has the authority to enter into this Agreement and bind McCowan Clinical Laboratory, Inc. on its behalf. The Agreement is binding upon Accreditee, its agents, managers, employees, representatives, shareholders, directors, officers, successors, and any and all persons or entities acting in concert or participation with or for it.
22. This Settlement Agreement and Final Order may be executed in one or more multiple counterparts, including facsimile, scanned, and electronically transmitted counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement.
23. Accreditee is aware of the right to a contested case hearing if this matter was not resolved with this Agreement and ORELAP proceeded with formal action. Accreditee is aware of the right to judicial review. Accreditee freely and voluntarily waives all rights to a contested case hearing and to all judicial review. Accreditee agrees to ORELAP's issuance of a final order incorporating this Agreement.
24. The signed and initialed Agreement must be submitted electronically to [steven.jetter@oha.oregon.gov](mailto:steven.jetter@oha.oregon.gov) and received by ORELAP by April 10, 2025 at 5:00 PM, or this settlement offer is deemed withdrawn.

### **Corrective Action Report**

25. Accreditee agrees to implement a corrective action report as follows:
  - a. Accreditee shall implement ORELAP approved corrective action report(s) to address the violations described in this Agreement. The corrective action reports shall be submitted through the Inspection Report in ODIE within 30 days of receipt of the Inspection Report by Accreditee.
  - b. Accreditee shall demonstrate compliance with the 2016 TNI Standard V1M5 1.7.3.7.b.v.a and 1.7.3.7.b.v.b for the incubating equipment used in the premises. Records showing compliance with these portions of the

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TNI Standard shall be emailed to [orelap.info@oha.oregon.gov](mailto:orelap.info@oha.oregon.gov) by 5:00 PM on April 30, 2025.

- c. Accreditee shall send copies of the previous quarter's incubator temperature check logbooks to [orelap.info@oha.oregon.gov](mailto:orelap.info@oha.oregon.gov) on the following schedule:
  - i. 2025 Quarter 2 sent by July 10, 2025.
  - ii. 2025 Quarter 3 sent by October 10, 2025.
  - iii. 2025 Quarter 4 sent by January 10, 2026.
- d. Accreditee shall ensure incubator temperature check logbooks sent to ORELAP identify if client samples of any matrix are present in the incubator when temperatures are out of the acceptable range. If client samples are present in the incubator with unacceptable temperatures, Accreditee shall explain actions taken to address non-compliant testing in the logbook submitted to ORELAP.

**IT IS SO STIPULATED.**

*GAYLE TROYER* Dated: 4/10/2025  
Gayle Troyer, on behalf of McCowan Clinical Laboratory, Inc.

*[Signature]* Dated: 4/10/2025  
Steve Jetter, ORELAP Manager  
Public Health Division, Oregon Health Authority

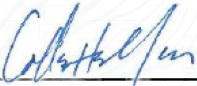
## FINAL ORDER

NOW THEREFORE, ORELAP finds and concludes that Accreditee committed 32 violations of OAR 333-064-0035(2)(b)(D) as described in the above Settlement Agreement.

FURTHER, ORELAP adopts all of the terms of the Settlement Agreement.

### IT IS SO ORDERED.

DATED this 10 day of April, 2025.

  
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Collette Young, Center Administrator,  
Center for Public Health Practice,  
Public Health Division, Oregon Health Authority